REMARKS

I. Introductory Comments

In the Office Action under reply, the Examiner has made the Restriction Requirement of January 10, 2006, final (although the Examiner has removed the species election) and has therefore withdrawn (without prejudice) claims 1-30 and 60-74 from further consideration. In addition, the Examiner indicated that the claims were rejected as follows: under 35 U.S.C. §112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention; and under 35 U.S.C. §102(b) as allegedly being anticipated by Andya et al. (U.S. Patent No. 6,267,958) (claims 31-59).

II. Amendments to the Specification and Claims

A. Specification Amendments

Paragraph **[0045]** has been amended to replace the incorrect word "spay" with the correct word -- spray --. Paragraph **[0175]** has been amended to delete the extraneous word "with." Each of these corrections addresses unintentional typographical errors identified in the specification. As a result, no new matter is introduced by way of these amendments.

B. Claim Amendments

Claims 1-74 were previously pending. Claims 31 and 51 are amended. Claims 1-30 and 60-74 were withdrawn from further consideration without prejudice by the Examiner. As a consequence, claims 31-59 remain under consideration.

Support for the changes to the claims is identified below. Additional support other than that identified below may exist in the originally filed application for one or more changes to the claims.

Claim 31 has been amended to indicate that the reconstituted composition is formed from "adding the diluent to" a spray-dried powder comprised of the antibody. Support for forming the reconstituted composition by adding the diluent to the spray-dried powder comprised of the antibody can be found in paragraph **[0106]** of the originally filed specification. As will be understood by one of ordinary skill in the art, adding the diluent to the spray-dried powder comprised of the antibody encompasses the step of adding the diluent to the spray-dried powder as well as adding the spray-dried powder to the diluent.

In addition, claim 31 has been amended to recite that the reconstituted composition "is a visually clear reconstituted composition within 10 minutes of being formed." Support for reconstituted compositions being visually clear within 10 minutes of being formed finds support in paragraph [0106].

Finally, the term "antibody fragment" has been deleted from claim 31 to maintain correct antecedent structure within the claims.

In claim 51, references to the surfactants "Tween-20" and "Tween-80" have been removed and replaced with a reference to –polysorbate --. Support for polysorbate as a surfactant is found in the first sentence of paragraph [0078].

As support for the changes is found in the application as filed, no new matter is introduced by the entry of the above-identified changes. The changes to the claims are made for clarification purposes only should not be interpreted as acquiescence in any claim rejection.

III. The Restriction Requirement

Applicants reserve their right to petition the Commissioner to review the requirement for restriction, deferring the filing of such petition until after final action on or allowance of the claims, but not later than appeal. See 37 C.F.R. §1.144.

IV. The Interview of June 29, 2006

At the undersigned's request, an interview with the Examiner and the Examiner's supervisor, Ms. Christina Chan, was conducted on June 29, 2006. During the interview, the propriety of one or more claim rejections was discussed (although no resolution was reached).

V. The Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner alleges that claim 51 fails to satisfy 35 U.S.C. 112, second paragraph, in that this claim recites the term "Tween." Upon entry of the claim amendments, claim 51 no longer recites the term "Tween," thereby rendering moot the Examiner's rejection. Consequently, for at least this reason, removal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

VI. The Rejection Under 35 U.S.C. §102(b)

The Examiner rejected of claims 31-59 under 35 U.S.C. §102(b) as allegedly being anticipated by Andya et al. (U.S. Patent No. 6,267,958). Ostensibly, the Examiner has taken the position that each and every element of the rejected claims can be found in Andya et al.

The rejection is respectfully traversed in view of the following remarks.

The standard for anticipation is rigorous requiring that every element of the claimed invention be disclosed by a single prior art reference. *See Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed.Cir.1992); *Scripps*, 927 F.2d at 1576-77; *Lindemann Maschinenfabrik GMBH, v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed.Cir.1984).

Upon entry of the amendments, each of the claims requires a reconstituted composition that is visually clear within 10 minutes of being formed. Thus, by indicating that the reconstituted composition at 10 minutes (or less) of being formed is a visually clear solution, Applicants have added a *product* feature to the claimed reconstituted composition. This *product* feature – visual clarity – is an indicator of complete reconstitution. See Applicants' specification at paragraph **[0151]**.

Such a product -- a reconstituted composition formed from a spray-dried composition -- stands in contrast to the reconstituted compositions formed from lyophilized compositions disclosed Andya et al. Specifically, Andya et al. discloses that the "time for required for reconstitution" of its lyophilized-based reconstituted compositions "will depend, e.g., on the type of diluent, amount of excipient(s) and protein." See Andya et al. at column 17, lines 23-26. Other than this passage, Andya et al. is completely silent with regard to reconstitution times.

Applicants, however, did conduct a head-to-head comparison of complete reconstitution times between (i) a reconstituted composition formed from a spray-dried composition, and (ii) a reconstituted composition formed from a lyophilized composition. Determination of complete reconstitution times was based on time to achieve visual clarity. See Applicant's specification at paragraph **[0151]**.

As reported in Applicants' specification at paragraph **[0162]**, "the spray-dried formulation reconstituted much faster than the corresponding lyophilized starting material at 200 mg/mL." In Table II that follows this paragraph, it is shown that the spray-dried formulation had a reconstitution time of less than 5 minutes while the lyophilized formulation had a reconstitution time of 11

minutes. Because complete reconstitution time was based on time to achieve visual clarity, the spray-dried-based reconstituted composition achieved visual clarity within 5 minutes while the lyophilized-based composition achieved visual clarity only at 11 minutes. As a consequence, the spray-dried-based reconstituted composition possessed the *product* feature of being visually clear within 10 minutes of being formed, a feature not associated with the lyophilized-based reconstituted composition.

In conclusion, Applicant's claim recites a *product* feature -- that of visual clarity within 10 minutes of being formed -- that is neither disclosed in Andya et al. nor shown to be an necessarily and inherent property lyophilized-based reconstituted compositions. Because Andya et al. do not teach (explicitly or inherently) each and every element of the claimed invention, the anticipation rejection cannot stand. Reconsideration and removal of the rejection under 35 U.S.C. 102(b) for at least the reasons provided above is respectfully requested.

VII. Conclusion

In view of the foregoing, Applicants submit that the pending claims satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all objections and rejections is respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 620-5506.

Respectfully submitted,
Nektar Therapeutics

Date: June 30, 2006

By: Mark A. Wilson

Mark A. Wilson
Registration No. 43,275

Nektar Therapeutics
150 Industrial Road
San Carlos, CA 94070
(650) 631-3100 (Telephone)
(650) 631-3125 (Facsimile)